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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/067,146 | 02/04/2002 | Frederick P. Siegal | 10034-004 | 7266 |

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| EXAMINER | |
|---|---|
| KAUSHAL, SUMESH | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1636 | |

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Advisory Action | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/067,146 | SIEGAL ET AL. | |
| | Examiner | Art Unit | |
| | Sumesh Kaushal Ph.D. | 1636 | |

*--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED 09 November 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *11,15 and 20-35*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

JEFFREY FREDMAN
PRIMARY EXAMINER
12/x

Continuation of 5. does NOT place the application in condition for allowance because: Claims 11, 15 and 20-35 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the same reasons of record as set forth in the office action mailed on 08/09/04.
Response to arguments
The applicant argues that the specification establish interferon production negatively correlates with HIV progression and positively correlates with the effectiveness of HIV treatment. The applicant argues that given this data, one skilled artisan would conclude that the quantity of pDC2 interferon producing cells negatively correlates with HIV progression and positively correlates with the effectiveness of HIV treatment. The applicant concluded that this correlation is sufficient to enable the invention as claimed. The applicant further argues that establishing a control range of pDC2 cells for healthy population would take only routine experimentation
However, applicant's arguments are found NOT persuasive because the disclosure "shall inform how to use, not how to find out how to use for themselves." See In re Gardner 475 F.2d 1389, 177 USPQ 396 (CCPA 1973). The specification as filed fails to establish any correlation between the number of pCD2-interferon-producing dendritic cells and the progression of HIV infection and/or AIDS. At best the specification only discloses evaluation of IFN-g production by total PBMCs or pDC2-depleted, pDC2-enriched mononuclear cells (pages 30-32). The specification as filed fails to provide any direct evidence that establishes there are changes in number of pCD2-interferon-producing dendritic cells during the progression of HIV-infection and upon treatment. In addition the cellular identity of IPC is the most important issue in the enumeration of IPC in a particular disease. For example it is important to establish whether these cells represent a unique lineage or do they belong to an already defined lineage of cells such as dendritic cells. In the instant case the scope of pCD2 phenotype as claimed encompasses a dendritic cells with any phenotype, whereas the instant specification only identify pCD2 cells as cells that are CD4+, CD3-, CD11c-. Furthermore the cellular distribution of pCD2 is not known, since appropriate tissue studies have not been performed to determine whether the cells are able to move out of periphery and into tissues. Therefore the identification of pCD2 phenotype is considered germane in evaluating the number of pCD2 cells in health or in HIV infection.
Furthermore the specification fails to establish the reference range (control sample) for pDC2 cells in context with HIV infection and/or AIDS using normal healthy individuals. The earlier office action clearly provided the evidence that there is a significant decrease of the circulating pDCs during ageing in healthy adult humans. In addition loss of pDC IFN-a generation by blood MNC attributable not only to declining pDC number but also to the reduction in IFN generated per pDC (Shodell et al Scand J. Imunol 56:518-521, 2002 see page 518 521). Therefore it is highly unpredictable to predict the number of pDC2 (as claimed) by evaluating the levels of IFN-g produced in a sample, since the specification fails to establish that the number of pCD2-interferon-producing dendritic cells correlates with the progression of HIV infection and/or AIDS.
In addition the cellular identity of IPC is the most important issue in the enumeration of IPC in a particular disease. For example it is important to establish whether these cells represent a unique lineage or do they belong to an already defined lineage of cells such as dendritic cells. In the instant case the scope of pCD2 cells as claimed encompasses a dendritic cells with any phenotype, whereas the instant specification only identify pCD2 cells as cells that are CD4+, CD3-, CD11c-. Furthermore the cellular distribution of pCD2 is not known, since appropriate tissue studies have not been performed to determine whether the cells are able to move out of periphery and into tissues. Therefore the identification of pCD2 is considered germane in evaluating the number of pCD2 cells in health or a disease resulting form HIV infection.
In addition monitoring the progression of HIV-infection or AIDS by evaluating the number of pDC2 (any phenotype) in a sample obtained form a blood or any lymphoid tissue of a subject having HIV infection is not considered routine in the art and without sufficient guidance to a specific disease/disorder and its correlation to number of pDC2 cells eliciting a specific phenotype, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). Therefore considering the state of the art and limited amount of guidance provided in the instant application one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed.